# PERFORMANCE RE-QUALIFICATION PROTOCOL FOR SHRINK WRAPPING MACHINE

| | |
|---|---|
| **LOCATION** | **OINTMENT SECTION , PACKING AREA** |
| **SUPERSEDES PROTOCOL No.** | **NIL** |

| PHARMA DEVILS | PERFORMANCE RE-QUALIFICATION PROTOCOL FOR SHRINK WRAPPING MACHINE | PROTOCOL No.: |
|---|---|---|

# PROTOCOL CONTENTS

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|---|---|---|

## 1.0 PROTOCOL APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |
| HEAD (PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |

## 2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

## 3.0 SCOPE:

- The Protocol covers all aspects of Performance Re-qualification for the Shrink Wrapping Machine (Equipment ID: ……., Make: ……) installed in Ointment section, Packing Area.
- The Shrink Wrapping Machine is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This Protocol will define the methods and documentation used to qualify the Shrink Wrap Machine for Performance Re-qualification.

## 4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol.

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| **Quality Assurance** | • Preparation, Review, Approval and Compilation of the Performance Re-qualification.<br>• Co-ordination with Production and Engineering to carryout Performance Re-qualification Activity.<br>• Monitoring of Performance Re-qualification. |
| **Production** | • Review of Performance Re-qualification Protocol.<br>• To co-ordinate and support Performance Re-qualification Activity. |
| **Engineering** | • Reviewing of Performance Re-qualification protocol.<br>• Responsible for trouble shooting (if occurred during execution).<br>• Maintenance & preventive maintenance as per schedule. |

## 5.0 EQUIPMENT DETAILS:

| | |
|---|---|
| **Equipment Name** | Shrink Wrapping Machine |
| **Equipment ID** | |
| **Manufacturer's Name** | |
| **Model** | GMP Model |
| **Supplier's Name** | |
| **Location of Installation** | Packing Area |

## 6.0 EQUIPMENT DESCRIPTION:

Vinpack provides Shrink Wrapping Machine is a very efficient machine, all around close design ensures less heat, thus less electricity consumption. Heavy duty conveyor system having insulated surface is provided to avoid any damage to product or shrink sleeve. High speed blower system provided with continuous rating. Shrink Wrapping Machine is equipped with high quality heating elements to create a recirculating air system that forces air to all package surfaces. Independent regulate system controls temperature, air velocity and conveyer speed. The efficient heating system on machine reduces the amount of electricity needed to run the machine consequently reducing the operating costs. Upper Centrifugal fan to ensure 360 degree airflow and uniform temperature distribution.

Machine can be attached with any other packing machine or operation to give online application.

Vinpack Shrink Wrapping Machine provides protection to the product and enhances its aesthetic value. Single or set of products can be elegantly packed together. This is one of the widely accepted tamper proof packing method for a variety of consumer and industrial products. It provides complete protection to the product from heat, moisture and dust, which enhances shelf life of the product.

## 7.0 REASON FOR RE-QUALIFICATION:

- Periodically as per qualification planner.
- After any major modification.

## 8.0 SITE OF STUDY:

- Packing Area.

## 9.0 FREQUENCY OF RE-QUALIFICATION:

- Once in a two year ± 01 month.

## 10.0 PRE - RE-QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance Re-qualification activity:

### 10.1 Training Record of Validation Team:

- All the persons involved in the execution of Re-qualification activity must be trained in all aspects of the Re-qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.

### 10.2 Calibration of Test Instruments:

- Calibration of all the instruments used for Re-qualification should be mentioned along with Calibration Certificates.

## 11.0 TESTS AND CHECKS:

### 11.1 Installation checks:

| S.No. | Installation Check | Acceptance criteria |
|---|---|---|
| 1. | Equipment Name | Shrink wrapping machine |
| 2. | Equipment Identification number | |
| 3. | Manufacturer Name | Vinpack Shrink Wrapping |
| 4. | Location of Installation | Packing area |
| 5. | Check the proper mechanical installation of Shrink Wrapping Machine. | Should be satisfactory |
| 6. | Check the proper electrical installation of Shrink Wrapping Machine. | Should be satisfactory |
| 7. | Check the parts are working properly. | Should be Properly working |
| 8. | Check the equipment is free from any defects. | Should be free from any defects. |
| 9. | Check the finishing of machine parts. | Should be satisfactory |

**11.2 Functional checks:**

Operate the Shrink wrapping machine as per manufacture's /SOP and checks for the Following Functions of The Equipment. The Equipment should function as desired.

| S.No. | Operation | Acceptance criteria |
|---|---|---|
| 1. | Check correct working of machine | The machine should be Operational |
| 2. | Press start switch | Machine should started |
| 3. | Press Stop switch | Machine should stopped |

**11.3 Power Failure verification:**

| S.No. | Checks | Acceptance Criteria |
|---|---|---|
| 1. | Main Power Shut Down | Equipment stops in a safe and secure condition. |
| 2. | Main Power Restored | Equipment can be restarted with no problems or adverse conditions. |

**11.4 Evaluation of Performance by Using Drug Product:**

**11.4.1 Objective:**

- The purpose of this test is to perform visual examination to ensure that the Sealing Quality. To verify that shrink packs are uniform in appearance, free from any visual defects, temperature remains within the specified limits.

**11.4.2 Method:**

- Performance Re-qualifications shall be performed at initial, middle & end of single batch.
- Affix the Data Logger sensor Such as

| Data Logger Sensor | Location |
|---|---|
| CH-01 | Upper Side of shrink pack |
| CH-02 | Inside Side of the Carton |

- Star the data logger & scan the temperature every 5 second.
- Data logger & sensor should be calibrated.
- Charge the shrink pack in Shrink Wrapping Machine.
- Load the approved wrapping material on Rolls.
- Set the temperature 140-160°C.
- Run the machine as per respective SOP.

- One sensor insert inside the carton and second sensor attached in upper side of shrink pack.
- Record the test data and any observations throughout the process.
- Samples are analysed for uniform wrapping as visually seen.

**11.4.3 Instrument:** All which are used for evaluation of Performance of Shrink Wrapping Machine should be calibrated**.**

- Digital Data Logger with sensor.

**11.4.4 Acceptance Criteria:**

- There should be no visual defects of shrink wraps.
- Shrink pack appearance should be uniform.
- Temperature should be recorded for information purpose.

## 12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Re-qualification Report. The list includes:

| S.No. | TESTS OR CHECKS |
|---|---|
| 1 | Installation checks |
| 2 | Functional checks |
| 3 | Power failure Verification |
| 4 | Evaluation of performance |

## 13.0 REFERENCES:

**The Principle References are as following:**

- Validation Master Plan.
- Operation and Cleaning of Shrink Wrapping Machine.

## 14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

## 15.0 NON COMPLIANCE:

- In case of any Non-compliance observed during re-qualification, same shall be handled through SOP for Handling of Non-Compliance.

## 16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during re-qualification, same shall be handled through SOP for Handling of Deviation.

## 17.0 CHANGE CONTROL, IF ANY:

- If any change is required during re-qualification, same shall be handled through SOP for Change Management.

## 18.0 ABBREVIATIONS:

| | | |
| --- | --- | --- |
| cGMP | : | Current Good Manufacturing Practices |
| ID. | : | Identification |
| PPQ | : | Performance Re-qualification Protocol |
| SOP | : | Standard Operating Procedure |
| SWM | : | Shrink Wrap Machine |
| PPQ | : | Performance Qualification Protocol |